PUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

JANET DIANE TALLEY,
Plaintiff-Appellant,

v. No. 98-1884

DANEK MEDICAL, INCORPORATED,
Defendant-Appellee.

Appeal from the United States District Court
for the Eastern District of Virginia, at Richmond.
Robert R. Merhige, Jr., Senior District Judge.
(CA-95-816-3)

Argued: January 25, 1999

Decided: July 12, 1999

Before ERVIN, NIEMEYER, and KING, Circuit Judges.

Affirmed by published opinion. Judge Niemeyer wrote the opinion,
in which Judge Ervin and Judge King joined.

COUNSEL

ARGUED: Martin Joseph McGetrick, Bradford Manson Young, CHANDLER, FRANKLIN & O'BRYAN, Charlottesville, Virginia, for Appellant. George Lehner, PEPPER HAMILTON, L.L.P., Washington, D.C., for Appellee. **ON BRIEF:** Gary J. Spahn, Dabney L. Carr, IV, MAYS & VALENTINE, L.L.P., Richmond, Virginia, for Appellee.

OPINION

NIEMEYER, Circuit Judge:

Janet Talley contends that her doctor's use, in a spinal fusion operation on her, of a Dyna-Lok Device, an internal fixation device manufactured by Danek Medical, Inc., caused her injury because orthopedic screws became loose and a bone graft in her spine did not properly fuse. In her complaint against Danek, she alleged breach of warranty, negligence, and fraud arising from Danek's marketing of the Dyna-Lok Device for a use not approved by the Food and Drug Administration (FDA) and Danek's negligent design of and inadequate warning about the device.

The district court granted Danek summary judgment on the grounds (1) that Talley failed to present the court with any admissible evidence of negligence and (2) that Danek's warranty and fraud duties did not extend to Talley because of the "learned intermediary" doctrine, limiting in certain circumstances a manufacturer's duty to warning only doctors and not their patients. See Talley v. Danek Medical, Inc., 7 F. Supp.2d 725 (E.D. Va. 1998). After considering Talley's arguments on appeal, we affirm, although through a somewhat different analysis.

I

In response to Janet Talley's complaints of sharp pain in her lower back, Dr. Andrea Wynn, an orthopedic surgeon in Winchester, Virginia, performed surgery on Talley to remove a small herniated disc. When Talley's condition failed to improve, Dr. Wynn referred Talley to Dr. Hallett Mathews, a well-known surgeon and professor in Richmond, Virginia, specializing in spinal surgery. Dr. Mathews had performed approximately 400 spinal surgeries using internal fixation devices, such as the Dyna-Lok Device.

In February 1992, Dr. Mathews removed the L4-5 disc from Talley's back and inserted a bone graft to promote fusion. He did not insert an internal fixation device. Despite this surgery and subsequent physical therapy, Talley's back condition did not improve. After con-

ducting a myelogram to identify other problems that might have contributed to Talley's pain, Dr. Mathews concluded that additional back surgery, including implantation of an internal fixation device, would be necessary.

Prior to Talley's third operation in October 1993, Dr. Mathews provided Talley with a pamphlet describing the Dyna-Lok Device, a surgical implant device used to immobilize parts of the spine as part of spinal fusion surgery. The device was manufactured and distributed by Danek Medical, Inc. Talley read the pamphlet and also glanced over a consent form before signing it. During the operation, Dr. Mathews removed disc material from Talley's spine to decompress the L4-5 and L5-S1 area, and he successfully implanted the Dyna-Lok Device. As after her previous surgeries, Talley was instructed to avoid excessive exercise or movement for several weeks, to wear a back brace when not in bed, and generally to avoid overusing her back so as not to loosen the screws on the Dyna-Lok Device.

Sometime after her third surgery, Talley began experiencing pain again in her back as well as in other areas. Dr. Mathews concluded that due to "excess motion" or "bad bone quality" or Talley's "not adhering to the guidelines after surgery," the bone screw interface had loosened and the loose screws had become a possible"pain generator." Accordingly, Dr. Mathews recommended further back surgery either to tighten the screws and to reattach the Dyna-Lok Device to the spine or to remove the device. Although Talley now states that she then understood the purpose of this fourth surgery to be the removal of the device, the consent form which she signed at the time authorized Dr. Mathews to perform "lumbar exploration of L4-5 with possible removal of Dyna-Lok (Titanium) fixation and possible regrafting with iliac crest autograft."

In February 1995, Dr. Mathews performed the fourth operation on Talley's back. Finding the Dyna-Lok Device intact but the screws loose, Dr. Mathews attempted to fuse the vertebrae again by grafting more bone fragments and reattaching the Dyna-Lok Device with larger screws. After surgery, Talley was again instructed to minimize physical activity and to wear a back brace. Although Talley appeared to be rehabilitating successfully for several months following surgery, in late 1995 she began to experience pain again. Dr. Mathews attri-

buted the pain to over-activity and the development of arachnoiditis, a nerve injury common among patients who have had multiple back surgeries.

Since her fourth operation, Talley has been examined by other doctors who have offered differing opinions as to the stability of the Dyna-Lok Device and the screws. A doctor at Georgetown University Hospital advised Talley that the Dyna-Lok Device was not loose; a doctor at Johns Hopkins University Hospital advised her that the device was loose. Although Talley has been advised to have the Dyna-Lok device removed, she consistently refuses such an operation without a guarantee that it will not worsen her condition.

During the period that Talley was Dr. Mathews' patient, Dr. Mathews served as a consultant to Danek, designing endoscopes and assisting in efforts to secure FDA approval for the use of the endoscopes in the spine -- work that is unrelated to the use of internal fixation devices. As part of this consulting arrangement, Dr. Mathews' office served as a "receptorship site" to teach surgeons surgical techniques involving both Danek products and other products. For these consulting services, Dr. Mathews received an annual consulting fee of $250,000, a travel budget, research funds, and 25,000 shares of stock in Danek Group, Inc., the parent of Danek Medical, Inc. Despite his affiliation with Danek, Dr. Mathews has used internal fixation devices other than the Dyna-Lok Device. According to Dr. Mathews, the system he uses depends on the individual patient-- specifically, "the length of the fusion, the angulation of the spine, or what kind of balance you have to restore." But Dr. Mathews explains that he prefers the Dyna-Lok Device because it is "user-friendly," "one of the cheapest systems out there cost wise," "predictable," and "easy to teach." Following Talley's surgeries, Dr. Mathews has continued to use the Dyna-Lok Device in spinal fusion surgeries.

In October 1995, several months after her fourth operation, Talley filed this action in the district court against Danek, relying on diversity jurisdiction and alleging negligence, breach of warranty, and fraud under Virginia law. In November 1995, the Judicial Panel on Multidistrict Litigation transferred this case to the Eastern District of Pennsylvania for Multidistrict Litigation discovery, and in December 1997, the Eastern District of Pennsylvania remanded the case to the

district court. Following Danek's motion for summary judgment, the district court entered summary judgment in favor of Danek on all counts. This appeal followed.

II

Talley contends first that she presented sufficient evidence of Danek's negligence to withstand a motion for summary judgment and entitle her to a jury trial. She maintains that there is a genuine dispute of material fact over whether Danek violated the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and that a violation of the FDCA constitutes negligence per se in Virginia. She also maintains that she presented sufficient expert testimony to establish negligence independent of the alleged FDCA violation. We address these theories in order.

A

The essential elements of a negligence claim in Virginia, as elsewhere, are (1) the identification of a legal duty of the defendant to the plaintiff; (2) a breach of that duty; and (3) injury to the plaintiff proximately caused by the breach. See Locke v. Johns-Manville Corp., 275 S.E.2d 900, 904 (Va. 1981). Under Virginia law,"[t]he standard of conduct to which a party must conform to avoid being negligent is that of a reasonable man under like circumstances." Moore v. Virginia Transit Co., 50 S.E.2d 268, 271 (Va. 1948) (citation and internal quotation marks omitted).

The standard of conduct of a "reasonable man" in a negligence case is generally determined by a jury on a case-by-case basis. Under the doctrine of negligence per se, however, the violation of a statute or ordinance can constitute a violation of the "reasonable man" standard as a matter of law. See Butler v. Frieden, 158 S.E.2d 121, 122 (Va. 1967). Thus, in negligence per se cases, the courts"adopt as the standard of conduct of a reasonable man the requirements of a legislative enactment or an administrative regulation." Restatement (Second) of Torts § 286 (1965); see also Butler, 158 S.E.2d at 122.

An example illustrates the doctrine's application. If the statutory speed limit on a road is 35 m.p.h. and the defendant drives 40 m.p.h.,

causing him to collide with the plaintiff pedestrian and to injure her, the plaintiff may establish the breach element of her negligence claim by pointing to the violation of the speed limit. The defendant is barred from putting on evidence, specific to his situation, that driving at 40 m.p.h. on that particular road was reasonable because the "violation of the statute constitutes conclusive evidence of negligence." Osborne v. McMasters, 41 N.W. 543, 544 (Minn. 1889); see also Butler, 158 S.E.2d at 123-24 (holding that an ordinance prohibiting dogs to go at large on any public street supplied the standard for determining whether the dog owner was negligent in letting a dog go unleashed).

The negligence per se doctrine, however, is not a magic transforming formula that automatically creates a private right of action for the civil enforcement, in tort law, of every statute. Rather, it has long been recognized as a moderate rule which simply substitutes a general legislative judgment for a specific judicial judgment in instances where the legislature has set forth the standard of conduct that a "reasonable man" must follow. This concept, which characterizes the doctrine of negligence per se in Virginia, see Williamson v. Old Brogue, Inc., 350 S.E.2d 621, 624 (Va. 1986), was well summarized by an early Minnesota court as follows:

> Negligence is the breach of legal duty. It is immaterial whether the duty is one imposed by the rule of common law requiring the exercise of ordinary care not to injure another, or is imposed by a statute designed for the protection of others. . . . The only difference is that in the one case the measure of legal duty is to be determined upon common law principles, while in the other the statute fixes it, so that the violation of the statute constitutes conclusive evidence of negligence, or, in other words, negligence per se. .. . All that the statute does is to establish a fixed standard by which the fact of negligence may be determined.

Osborne, 41 N.W. at 544. But the negligence per se doctrine does not create new causes of action. Rather, it recognizes a legislatively created standard of care "to be exercised where there is an underlying common-law duty." Williamson, 350 S.E.2d at 624.

Moreover, liability in tort does not follow automatically from the breach of a legislatively defined standard of care. Virginia law makes

clear that a plaintiff who has established breach by relying on negligence per se must also establish the other elements of a negligence claim in order to prevail. Thus, the plaintiff must show that the "injured person is a member of a class for whose benefit the legislation was enacted" to establish the duty element. Butler, 158 S.E.2d at 122; see also Johnson v. J. S. Bell, Jr. & Co., 117 S.E.2d 85, 88 (Va. 1960). The plaintiff must also show that the breach of duty was a proximate cause of the plaintiff's injury. See Bentley v. Felts, 445 S.E.2d 131, 133 (Va. 1994). In our speed limit scenario, for example, the plaintiff would prevail if she could show that the speed limit statute was intended, as it surely was, to protect pedestrians and that the violation of the statute was a proximate cause of her injuries.

Thus, the potential for the negligence per se doctrine to become a mechanism to enforce any statute through a private right of action is cabined in at least two ways. First, not all statutory provisions dictate a standard of care, and therefore not all statutory violations can provide a basis for establishing negligence per se. Second, even when a statutory provision does specify a standard of care, a plaintiff must still prove the additional elements of duty, proximate causation, and injury to establish liability.

Where a statutory provision does not define a standard of care but merely imposes an administrative requirement, such as the requirement to obtain a license or to file a report to support a regulatory scheme, violation of such requirement will not support a negligence per se claim. Even if the regulatory scheme as a whole is designed to protect the public or to promote safety, the licensing duty itself is not a standard of care, but an administrative requirement. See Ridge v. Cessna Aircraft Co., 117 F.3d 126, 131 (4th Cir. 1997) (holding that federal regulations making a pilot responsible for operation of his aircraft and requiring him, upon request, to submit a written report to the government whenever he deviates from an aviation rule in an emergency provide for "general standards of conduct," but do "not impose a particular duty," and thus their violation was not negligence per se in Virginia); see also Duncan v. Hixon, 288 S.E.2d 494, 495 (Va. 1982) (observing that "[i]n a majority of accident cases, the violation of a licensing statute by a driver is not held relevant to the determination of fault").

The analytical distinction between determining whether a licensing requirement establishes a standard of care and determining whether a violation of such a requirement is a proximate cause of plaintiff's injury can often become blurred, and the Virginia courts have been more inclined to resolve negligence per se claims based on licensing requirements by concluding that the violation of a licensing requirement is not a proximate cause of the injury. See Laughlin v. Rose, 104 S.E.2d 782, 786 (Va. 1958) (finding that the lack of a driver's license, albeit a statutory violation, "did not proximately cause or contribute to the collision"); White v. Edwards Chevrolet Co., 43 S.E.2d 870, 871 (Va. 1947)(remarking that driving a truck after expiration of a permit did not cause injury, just as "the failure of a competent driver to obtain a chauffeur's license could not, by any possibility, have contributed proximately to the happening of the automobile collision complained of" (citations and internal quotation marks omitted)); see also Bentley, 445 S.E.2d at 133 (observing that"[v]iolation of a traffic statute constitutes negligence, but imposition of liability depends on whether that negligence was a proximate cause of the accident"). As Professors Prosser and Keeton have reasoned,"[w]hen a car is driven without a license, the act of driving the car certainly causes a collision; the absence of the license, or the existence of the statute, of course does not." W. Page Keeton et al., Prosser & Keeton on Torts § 36, at 223-24 (5th ed. 1984).

In summary, where a particular statutory requirement does not itself articulate a standard of care but rather requires only regulatory approval, or a license, or a report for the administration of a more general underlying standard, violation of that administrative requirement itself is not a breach of a standard of care. This violation rather indicates only a failure to comply with an administrative requirement, not the breach of a tort duty. By analogy, such a violation also cannot be the proximate cause of the injury. Accordingly, in this case we must determine whether Danek's alleged violation of statute amounted to the breach of an administrative requirement or the breach of a standard of care and whether such a breach proximately caused Talley's injury.

Talley alleges that Danek marketed a surgical device for a use that had not been approved by the FDA and that that violated the FDCA and therefore established negligence per se. See 21 U.S.C. § 360e(a)

(requiring premarket approval for Class III medical devices); see also 21 U.S.C. §§ 331(a)(prohibiting the introduction of adulterated or misbranded devices into interstate commerce), 351(f)(1) (defining adulterated devices to include unapproved Class III devices). Under the FDCA, the FDA has the jurisdiction to regulate drugs and medical devices that are sold in interstate commerce, and most new drugs and many medical devices cannot legally be sold in interstate commerce without FDA approval. See 21 U.S.C. § 355(a) (drugs); 21 U.S.C. § 360c(a)(1)(C) (medical devices). These drugs and devices undergo rigorous testing to demonstrate both "safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C); see also 21 U.S.C. 360e(d)(2); 21 U.S.C. § 355(d). When the FDA is satisfied that a drug or device is both safe and effective it will give its approval, which is tantamount to a required license to sell the drug or device in the United States.

The Medical Device Amendments of 1976 to the FDCA classify medical devices into three categories, based on the risk that they pose. See 21 U.S.C. § 360c(a). Devices that pose a low risk are classified as Class I devices and are subject to minimal regulations such as registration and premarketing notification. See 21 U.S.C. § 360c(a)(1)(A). Devices that pose a somewhat greater risk of harm are classified as Class II devices. See 21 U.S.C. § 360c(a)(1)(B). The majority of medical devices fall into this class. See Frank D. Nguyen, Regulation of Medical Expert Systems: A Necessary Evil?, 34 Santa Clara L. Rev. 1187, 1206 (1994) ("Class II devices include syringes, bone plates, hearing aids, resuscitators, and electrocardiograph electrodes"). Although Class II devices may be marketed without premarket approval, they are subject to "special controls . . . that are necessary to provide adequate assurance of safety and effectiveness." 21 U.S.C. § 360c(a)(1)(B). Finally, Class III devices, which are deemed to pose the greatest risk of harm, require FDA approval prior to general sale. See 21 U.S.C. § 360c(a)(1)(C); 21 U.S.C. § 360e; see generally, Medtronic, Inc. v. Lohr, 518 U.S. 470, 476-80 (1996). The FDA, using panels of experts, classifies all devices intended for human use into the three classes and effects any changes to classifications. 21 U.S.C. § 360c(b), (e).

At the time of Talley's surgery, pedicle screw fixation devices were classified by the FDA as Class III devices, meaning that they could not be sold without FDA approval, and, the parties agree, the

Dyna-Lok Device was not then approved for use in the pedicles of the spine. The parties also agree, however, that the Dyna-Lok Device was considered a Class II device for another medical purpose and therefore could lawfully be sold. Talley contends that while purportedly selling the Dyna-Lok Device for its Class II purpose, Danek was in fact marketing the device for the unapproved Class III purpose of use in the pedicles of the spine, an allegation that Danek denies. Talley further contends that this action -- marketing an approved device for an unapproved use -- constitutes a violation of the FDCA that supports a negligence per se claim. Even assuming, however, that there is a genuine dispute of fact over whether Danek was marketing the device for use in the pedicles of the spine in violation of the FDCA, Talley's claim fails. She has not demonstrated either that marketing the device without FDA approval violated a standard of care or that the absence of FDA approval had any causal relationship to her injury.

Talley relies on our decision in Orthopedic Equipment Co. v. Eutsler, 276 F.2d 455 (4th Cir. 1960), to advance her claim that any violation of the FDCA constitutes negligence per se in Virginia. In that case we held that the misbranding of a bone nail, by wrongfully imprinting a dimension on the nail indicating that it would fit into a 9mm hole, violated a standard of care that would support a negligence per se claim under Virginia law. In that case, the plaintiff had undergone surgery in which the bone nail was to be inserted into the plaintiff's femur (thigh bone). When the surgeon sought to insert the nail into a 9mm hole, it would not fit properly because the misbranded nail was too large. The attempted insertion caused the plaintiff to lose the use of his leg. We held that the statutory requirement to label a surgical nail with the correct size on it established a standard of care because the mislabeling created an unreasonable risk for patients. Id. at 461. The alleged violation in Eutsler, however, is distinguishable from the alleged violation in Talley's case.

Breach of the requirement not to misbrand a surgical nail is similar to a breach of a speed limit; each violates a specific and substantive standard of care that is intended to protect others. The holding in Eutsler, however, does not establish the principle that the simple failure to obtain approval of a device from the FDA, standing alone, can support a negligence per se claim. The administrative requirement

that a given device be approved by the FDA before being marketed -- as opposed to a specific substantive requirement that a device be safe and effective -- is only a tool to facilitate administration of the underlying regulatory scheme. Because it lacks any independent substantive content, it does not impose a standard of care, the breach of which could form the basis of a negligence per se claim. Its breach is analogous to the failure to have a drivers license.

In concluding that the FDCA requirement for prior approval of a medical device does not itself support a claim for negligence per se, we do not intend to trivialize the alleged violation of administrative statutory provisions. They are essential to the underlying federal regulatory scheme that serves important societal interests. But because such specific approval rules are administrative, they do not amount to a legislative judgment as to the standard of care, and accordingly, breach of these provisions in themselves cannot underlie a negligence per se claim.

Also fatal to her theory, Talley has failed to present evidence that the breach of the FDA approval requirement proximately caused any failure of the Dyna-Lok Device and injury to her back. If the quality or proper labeling of the device, rather than its formal approval, were at issue, then causation might have become a question of fact. But that was not the circumstances here. Indeed, pedicle screw fixation devices were reclassified as Class II devices on July 27, 1998. See Orthopedic Devices: Classification and Reclassification of Pedicle Screw Spinal Systems, 63 Fed. Reg. 40025 (1998) (to be codified at 21 C.F.R. § 888). Thus, not only is the Dyna-Lok Device safe to market for use in spinal fusion surgery, but it presumably was also safe at the time of Talley's surgeries. More important to the issue of causation, Dr. Mathews' use of the device has never been linked to any promotion by Danek. Although Dr. Mathews knew that the device had not been approved for use in the pedicles of the spine, he apparently used it in this way based on his independent professional judgment as evidenced by his use of such devices hundreds of times before their approval and his continued use of them, without interruption, after approval. The FDA's approval vel non at any point in time has not been shown to have affected Dr. Mathews' conduct or his views about the merits of the device.

For these reasons, we conclude that Talley cannot rely on the doctrine of negligence per se to maintain her negligence claim.

B

Talley has also sought to establish her negligence claim on the basis that the Dyna-Lok Device was an unreasonably dangerous product because of defective design and engineering. See Morgen Indus., Inc. v. Vaughan, 471 S.E.2d 489, 492 (Va. 1996). To succeed on this theory, Talley would have to show that the Dyna-Lok Device "contained a defect which rendered it unreasonably dangerous for ordinary or foreseeable use." Alevromagiros v. Hechinger Co., 993 F.2d 417, 420 (4th Cir. 1993). As support for this theory, Talley relied on the expert testimony of Dr. Franklyn O'Rourke and Dr. Harold Alexander.

Dr. O'Rourke opined that the Dyna-Lok Device was negligently designed because the orthopedic screws were too short. He conceded, however, that he did not know the actual length of the screws. Furthermore, his opinion that the screws were too short had no apparent support in the record. We believe the district court was well within its discretion to disregard this entirely speculative testimony in considering the motion for summary judgment. See Alevromagiros, 993 F.2d at 421; see also Tyger Constr. Co. v. Pensacola Constr. Co., 29 F.3d 137, 142 (4th Cir. 1994) (stating that "[a]n expert's opinion should be excluded when it is based on assumptions which are speculative and are not supported by the record").

Dr. Alexander testified that there was an industry dispute as to whether fusion procedures using spinal fixation devices were more likely to be successful than fusion procedures that did not use spinal fixation devices. This testimony, however, did not indicate any design flaw in the Dyna-Lok Device. Rather, it questioned the medical judgment of doctors who use spinal fixation devices in surgery. While such an opinion might be relevant in a malpractice suit against a doctor, it is irrelevant in a suit against the product manufacturer. Thus, the district court did not abuse its discretion in refusing to consider this evidence in a suit against the manufacturer of a spinal fixation device.

In summary, we agree with the district court's conclusion that Talley "has failed to come forth with admissible evidence which would permit a jury to conclude that the Dyna-Lok Device was defectively designed." Talley, 7 F. Supp.2d at 732. And to the extent that Talley's breach of warranty and fraud claims rely on the same allegations of defective design, they too must fail.

III

Talley's breach of warranty and fraud claims are also based on allegations that the Dyna-Lok Device was not suitable for use in spinal surgeries and did not contain "sufficient instruction concerning its spinal application." In addition, Talley alleged that Danek fraudulently marketed the device, knowing that it had not been approved by the FDA for that purpose. The district court concluded that the breach of duties alleged by Talley in these claims was essentially a failure to warn and that, under the "learned intermediary" doctrine, Danek was only required to warn physicians and not their patients. See Abbot v. American Cyanamid Co., 844 F.2d 1108, 1115 (4th Cir. 1988) (citing Pfizer, Inc. v. Jones, 272 S.E.2d 43, 44 (Va. 1980)); Stanback v. Parke, Davis & Co., 657 F.2d 642, 644 (4th Cir. 1981) (noting the lack of Virginia authority on the learned intermediary doctrine but assuming that the Virginia Supreme Court "would follow the general rule" and adopt it).

The learned intermediary doctrine provides an exception to the general rule imposing a duty on manufacturers to warn consumers about the risks of their products. See Reyes v. Wyeth Lab., 498 F.2d 1264, 1276 (5th Cir. 1974). For products requiring prescription or application by physicians, the doctrine holds that a manufacturer need only warn doctors and not consumers. The doctrine is based on "sound policy considerations," as we have noted previously:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed

> on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

Stanback, 657 F.2d at 644 n.2 (quoting Reyes, 498 F.2d at 1276); see also Brooks v. Medtronic, Inc., 750 F.2d 1227, 1231 (4th Cir. 1984). For physician-prescribed drugs and medical devices, the physician "is in the best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment." Brooks, 750 F.2d at 1231.

The manufacturer, on the other hand, generally has no ability to assess the suitability of its product for a particular patient in a particular situation. Manufacturers of ethical drugs (i.e. drugs administrable only by a doctor's prescription) and medical devices make products which, while generally beneficial when used properly in the right circumstances, are often inherently dangerous when used improperly or in improper circumstances. The manufacturer lacks precisely the patient-specific information the physician possesses and uses to determine if, when, and how an ethical drug or device should be used.

In addition, practical realities support the learned intermediary doctrine because "it is virtually impossible in many cases for a manufacturer to directly warn each patient." Hill v. Searle Lab., 884 F.2d 1064, 1070 (8th Cir. 1989). While a manufacturer can enclose warnings with the product, when the product is applied directly by the physician -- as is the Dyna-Lok Device -- there is no practical way that the manufacturer could ensure that the patient receives the written warnings. Even if the manufacturer could be assured that the patient received the warnings, this practice might not be beneficial because "the information regarding risks is often too technical for a patient to make a reasonable choice." Id. One of the important functions of the physician is to determine the risks and to explain them to the patient in a way that can be understood.

Accordingly, in circumstances where (1) ethical drugs or medical devices that can be prescribed or installed only by a physician are

involved and (2) a physician prescribes the drug or installs the medical device after having evaluated the patient, the manufacturer of the drug or device owes the patient only the duty to warn the physician and to provide the physician with adequate product instructions.

Talley argues in this case that the learned intermediary doctrine should not apply because Dr. Mathews was not independent of Danek in view of his financial connection with Danek as a consultant. She argues, therefore, that he cannot be considered an intermediary, learned or otherwise.

It is true that in order for the doctrine to apply, the physician "must be an intervening and independent party between patient and manufacturer." Hill, 884 F.2d at 1070; cf. Reyes, 498 F.2d at 1276 (holding that the learned intermediary doctrine did not apply where dispensing agencies of a polio vaccine were not necessarily doctors making individualized judgments). Thus, if Dr. Mathews were an employee of Danek or so closely related to Danek that he could not exercise independent professional judgment, a question could legitimately be raised as to whether he was an intermediary. The resolution of that complex question would depend on the nature of the relationship between the manufacturer and the physician and the extent to which the physician was in fact afforded independence in making medical judgments.

In this case, however, there is no evidence that the consulting relationship between Dr. Mathews and Danek interfered with Dr. Mathews' independent medical judgment in treating Talley. On the contrary, the evidence suggests otherwise. The record shows that Dr. Mathews was not committed automatically to the installation of the Dyna-Lok Device. In fact, during his first operation on Talley's back, he attempted a fusion without implanting any internal fixation device. Moreover, the evidence shows that Dr. Mathews' selection of the kind of device to implant in a particular case was determined by the circumstances of the individual case. Dr. Mathews did not always choose to implant the Dyna-Lok Device. Rather, depending on a patient's physical circumstances, he sometimes installed similar devices made by competing manufacturers. Finally, Dr. Mathews' consulting relationship with Danek involved devices other than internal fixation devices.

For the foregoing reasons, we believe that the district court correctly applied the learned intermediary doctrine to bar Talley's claims based on a lack of notice and inadequate instruction.

Accordingly, the judgment of the district court is

AFFIRMED.